IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

THE PROCTER & GAMBLE CO , Plaintiff, v TEVA PHARMACEUTICALS USA, INC , Defendant	Civil Action No 04-940 (JJF)

PLAINTIFF THE PROCTER & GAMBLE COMPANY'S
OPPOSITION TO DEFENDANT'S MOTION TO CONSOLIDATE

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I. INTRODUCTION

In arguing that the above-captioned matter should be consolidated with the case captioned *Merck and Company v. Teva Pharmaceuticals USA, Inc.*, C.A. No. 04-939 (JJF), defendant Teva Pharmaceuticals USA, Inc. ("Teva") erroneously asserts that the actions involve "identical subject matter." Such a characterization of the facts and issues that are likely to develop in the respective actions is superficial, at best. Both actions arise out of Teva's filing of an Abbreviated New Drug Application ("ANDA") seeking approval to manufacture and sell a generic version of The Procter & Gamble Company's ("P&G") drug Actonel®, which is covered by various patents owned by P&G and Merck and Company ("Merck"). Teva chose to notify P&G and Merck of its ANDA filing in a single Paragraph IV notification. There the similarities end. The two actions involve different plaintiffs, different patents, different claim construction issues, different infringement analyses, different validity issues, and different fact and expert witnesses. Therefore, while P&G is willing to coordinate discovery and other pretrial proceedings to the extent possible in an effort to promote judicial economy and convenience to the Court and the parties, formal consolidation of the cases for trial or any other purpose is not supported by either the facts of the cases nor the law of this Court. Moreover, given the parties' informal agreement to proceed with discovery and pretrial proceedings on the same schedule, there is no need for the Court to address this issue at this early stage of the litigation. Accordingly, the Court should either deny Teva's Motion, or alternatively, defer ruling on the Motion until just prior to trial, so that the Court can make a more informed decision about the potential overlap (or lack thereof) based on actual facts in the record.

II. NATURE AND STAGE OF PROCEEDING

This is an action for patent infringement pursuant to 35 U.S.C. § 271(e)(2)(A) filed by P&G against Teva arising out of Teva's filing of an Abbreviated New Drug Application ("ANDA") seeking approval to manufacture and sell a generic version of The Procter & Gamble Company's ("P&G") drug Actonel® The Complaint (D.I. 1) was filed on August 13, 2004. P&G filed a First Amended Complaint (D.I. 5) on August 25, 2004. Teva filed an Answer (D.I. 8) to the First Amended Complaint on October 4, 2004. The parties agreed to and submitted a Rule 16 Scheduling Order (D.I. 10) on February 8, 2005. Since that time, the parties have exchanged initial disclosures. In addition, P&G has served its first set of document requests on Teva.

III. SUMMARY OF ARGUMENT

1. Consolidation is unwarranted because the two pending cases involve different patents, each raising distinct legal and factual issues with respect to claim construction, infringement, and validity.

2. Alternatively, the Court should defer deciding whether to consolidate until just prior to trial, at which time the Court can make a more informed decision about the potential overlap (or lack thereof) based on actual facts in the record.

IV. STATEMENT OF FACTS

P&G manufactures and sells Actonel®, which is indicated for the treatment of osteoporosis and Paget's disease of the bone. Actonel® is covered by claims of U.S. Patent No. 5,583,122 (the "'122 patent"), entitled "Pharmaceutical Compositions Containing Geminal Diphosponates," which P&G owns by assignment. The '122 patent generally claims compounds, pharmaceutical compositions, and methods of treatment that include risedronate, the active ingredient in Actonel®.

Particular dosing regimens for administering Actonel® are covered by three patents owned by Merck – U S Patent Nos 5,994,329, 6,432,932 B1, and 6,465,443 B2 (collectively, the "Merck patents"), all entitled "Method for Inhibiting Bone Resorption" – that P&G has licensed from Merck The Merck patents relate to particular dosing schedules (*i.e.*, once-weekly, twice-weekly, biweekly and twice-monthly dosing) and specific dosage forms of the broad class of bisphosphonates, including risedronate

In July 2004, Teva sent a Paragraph IV notification to P&G informing P&G that it had submitted to the Food and Drug Administration ("FDA") an ANDA seeking approval to market a generic version of Actonel® Teva's Paragraph IV letter asserted that the '122 patent was invalid, unenforceable, or not infringed by Teva In that same letter, a copy of which was also sent to Merck, Teva also made assertions concerning U S Patent No 5,994,329 (the "'329 patent").[1]

P&G subsequently filed the present action against Teva alleging infringement by Teva of at least claims 4, 16, and 23 of the '122 patent (C A No 04-940) Merck filed a separate action against Teva (C A 04-939) for infringement of various claims of the Merck patents Both cases are now pending before this Court

Teva now seeks to consolidate the actions for all purposes

V. ARGUMENT

Pursuant to Fed R Civ P 42(a), a court may consolidate all or part of two actions when they present "common question[s] of fact or law" Fed R Civ P 42 Whether to order consolidation is a matter of "sound judicial discretion" *La Chemise Lacoste v. The Alligator Co., Inc.*, 60 F R D 164, 175-76 (D Del 1973) (denying

[1] The letter further discussed two other patents assigned to P&G, and one other patent assigned to Merck However, these additional patents were not asserted by P&G or Merck, respectively

consolidation where cases were not "sufficiently connected"), and the "mere existence of common issues ... does not require consolidation"); *see also U.S. v. Dentsply Intl., Inc.*, 190 F.R.D. 140, 143 (D. Del. 1999); *Rohm and Haas Co. v. Mobil Oil Corp.*, 525 F. Supp. 1298, 1309 (D. Del. 1981) (although common issues of law or fact are prerequisite to consolidation, the "mere existence of such issues does not require a joint trial as a matter of course"). In determining whether to consolidate actions, courts balance savings of time and effort gained through consolidation against inconvenience, delay, or expense that it might cause. *U.S. v. Dentsply Intl., Inc.*, 190 F.R.D. at 143 (denying consolidation on public policy grounds).

A. Consolidation Is Unwarranted Because The Two Pending Cases Involve Different Patents, Each Raising Distinct Legal And Factual Issues.

This Court has refused to order consolidation in cases involving different patents, even where the patents involved certain similar subject matter. *See, e.g., Syngenta Seeds, Inc. v. Monsanto Co.*, 2004 WL 2002208, *2 (D. Del. 2004) (refusing to consolidate in part because adding additional patent would greatly increase complexity); *Clopay Corp. v. Newell Cos., Inc.*, 527 F. Supp. 733, 736-37 (D. Del. 1981) (denying motion to consolidate where different patents were at issue in each case).[2]

1. The '122 Patent And The Merck Patents Are Markedly Different.

In attempting to justify its request for consolidation, Teva incorrectly claims that the '122 patent and the Merck patents constitute "identical subject-matter," (D.I. 16 at 1),

[2] Though Teva claims that the "presence...of related technology in two cases is 'typically' a ground for consolidating them," (Defendant's Memorandum in Support of Consolidation, "Teva Br." at 4), the sole case relied upon by Teva, *Western States Machine Co. v. S.S. Hepworth Co.*, 37 F. Supp. 377 (E.D.N.Y. 1941) is a 1941 case from a different jurisdiction. In any event, unlike here, consolidation in that case was approved in part because both cases involved an analysis of the same centrifugal separators.

and wrongly characterizes P&G's explanation of the differences between the patents[3] as "misleading." *Id* at 4. Notwithstanding Teva's contentions, however, the '122 patent and the Merck patents are in fact substantially different.

The claims of the '122 patent relate primarily to the discovery of novel bisphosphonate compounds, including risedronate, and are directed to the compounds, pharmaceutical compositions and methods of treatment using such compounds.[4] By contrast, the Merck patents relate to later-developed technology and predominantly claim ***specific dosing regimens*** (*i.e.*, once-weekly, twice-weekly, biweekly and twice-monthly dosing), as well as compositions and kits useful in such dosing regimens.[5]

Thus, Teva's assertion that the issues in the two cases are the same – whether Teva's generic risedronate infringes either the '122 patent or the Merck patents and whether those patents are valid – is an overbroad and insupportable generalization. In reality, the differences between P&G's '122 patent and the Merck patents are inevitably going to create unique issues that would render consolidation unnecessary and ineffectual.

As an initial matter, the distinct claims in the '122 patent and the Merck patents necessarily will require the Court to construe different claim terms, which will be the subject of separate *Markman* briefs, and to conduct different infringement analyses. For example, notwithstanding Teva's current position that the patents contain "identical subject matter," in its Paragraph IV letter, it articulated wholly different bases for its assertions that the P&G '122 patent and the Merck '329 patent are not infringed. Teva

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[3] *See* P&G's February 22, 2005 letter to the Court, stating "the patents at issue in each suit are completely different in kind." (D.I. 12.)

[4] A copy of the claims of the '122 patent is attached hereto as Exhibit A.

[5] Copies of the claims of the Merck patents are attached hereto as Exhibits B-D, respectively.

offered no explanation as to why it does not infringe claims 4, 16, and 23 of P&G's '122 patent. In contrast, with respect to Merck's '329 patent, Teva asserted, *inter alia*, that it would not directly infringe that patent because it would not administer the generic risedronate tablets to patients, and that it does not recommend or suggest administration of such tablets in the way claimed by the '329 patent so as to induce or contribute to infringement of that patent.

Likewise, validity issues will also differ, as different purported prior art will be separately relevant to the '122 patent and the Merck patents. In fact, the application which became the '122 patent was filed over 12 years before the earliest Merck patent application from which priority is claimed for the Merck patents.[6] Therefore, over a decade of research and publications could possibly be material to the question of validity of the Merck patents but not to P&G's '122 patent. The potential invalidity grounds for the '122 patent and the Merck patents will thus differ greatly.

Indeed, Teva's Paragraph IV letter alleges different bases for claiming that the Merck '329 patent and the '122 patent are allegedly invalid. For example, Teva asserted primarily that P&G's '122 patent is anticipated and/or rendered obvious primarily by another P&G patent, U.S. Patent No. 4,761,406 (the "'406 patent"). On the other hand, with respect to the Merck '329 patent, Teva contended that it is anticipated and/or rendered obvious by, among other things, a *Lunar News* article, with no mention of the '406 patent.

As a result of these numerous distinctions between the '122 patent and the Merck patents, different fact and expert witnesses will be required to testify and opine on

[6] The earliest application from which priority is claimed for the '122 patent was filed December 21, 1984. The earliest application from which priority is claimed for the Merck patents was filed July 22, 1997.

unrelated issues of infringement and validity For example, the named inventors on the '122 patent – James J. Benedict and Christopher M. Perkins - are different than the inventors named on the Merck patents - Anastaia G. Daifotis, Arthur C Santora, II, and A John Yates In addition, different attorneys prosecuted the '122 patent and the Merck patents Moreover, while it is too early at this time to identify with certainty the witnesses who will be called by each of the parties, P&G is not presently aware of any present or former employees of Merck on whom it will rely as witnesses at trial

Finally, given that the issues for claim construction and determination of validity and infringement will differ, it is highly likely that much of the documentary evidence required to prove each case will also be different Therefore, because each case will likely involve unique facts, legal issues, witnesses, and documentary proof, the cases are not sufficiently connected to warrant consolidation *See Clopay Corp.*, 527 F. Supp at 735-36 (consolidation unwarranted because not efficient use of judicial resources); *La Chemise Lacoste*, 60 F R D at 176 (denying consolidation where cases did not involve sufficient common factual and legal questions).

2. Administration Of The Multiplicity Of Issues And Evidence Outweighs Any Possible Advantages To Consolidation.

Contrary to Teva's assertion that consolidation presents "nothing but advantages for the parties and the Court" (D I 16 at 1), consolidation at trial would instead considerably ***disadvantage*** all involved As described in detail above, adjudication of this case will involve numerous different fact and expert witnesses who will be called to testify on distinct infringement and validity issues relating separately to P&G and Merck, and their corresponding patents Injecting such a multiplicity of issues and witnesses into one proceeding will at best yield no efficiencies, and, at worst, could make administration

of the proceedings more difficult and time-consuming Accordingly, this Court should exercise its discretion to reject consolidation *See Clopay*, 527 F Supp at 736 (consolidation unwarranted where movant fails to persuade the Court that consolidation "represents the most efficient use of judicial resources or would reliably tend to avoid unnecessary costs or delay")

B. Alternatively, The Court Should Defer Deciding Whether To Consolidate Until Just Prior To Trial.

Although neither the facts nor the law favor the ultimate consolidation of these cases for trial, there is no immediate urgency for the Court to decide Teva's request for consolidation P&G is willing to coordinate its discovery and pre-trial efforts with Merck and Teva where possible, and, to this end, has agreed to a Rule 16 Scheduling Order identical to that agreed upon by Teva and Merck As a result, both cases will move forward on the same schedule for discovery and pre-trial proceedings Should the Court wish to reconsider Teva's request for consolidation prior to trial, it may then do so with the benefit of a full factual record and a more complete understanding of both the factual and legal issues involved

CONCLUSION

For the foregoing reasons, P&G respectfully requests that Teva's Motion to Consolidate this matter with Civil Action No. 04-939 (JJF) be denied, or alternatively, be deferred until just prior to trial.

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